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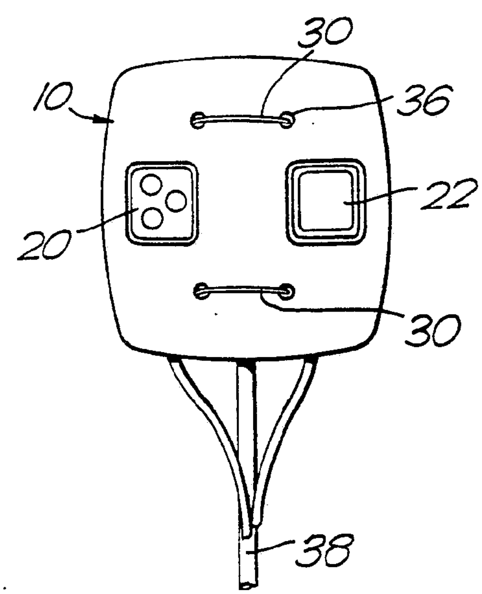

(57) Abstract

A fetal probe contains both an ECG electrode and photo transmitter-receiver means for measuring fetal blood oxygenation through light absorption. The electrode may take the form of a pair of metal spurs actuable remotely along the probe lead to pierce and grip fetal scalp skin.

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FETAL PROBE

This invention relates to obstetrics and more particularly to fetal probes.

Continuous or intermittent monitoring of the fetus has become an important aspect in the modern management of labour. In the aim to watch for fetal distress, fetal oxygenation in labour is monitored indirectly through an assessment of the fetal heart rate pattern; this is usually done with cardiotocographs (CTG's), also called electronic fetal monitors, and the R-wave of the electrocardiograph waveform is transmitted and displayed. For an interpretable CTG, an adequate, continuous signal has to be obtained from the fetus. The most reliable means to obtain a good signal is to apply an electrode directly to the fetal skin, by means of a single thin curved wire which pierces and imbeds in the fetal scalp. Modern designs of such 'fetal scalp electrodes' have increased their safety and acceptability for routine use in labour.

Through such monitoring, a perceived abnormality of the fetal heart rate pattern can be acted upon, e.g. by performing a Caesarean section. However, there is a high false-positive rate of diagnosing fetal distress with CTG alone, and it has been shown that an unnecessarily high rate of operative intervention can result. Therefore, in the presence of an abnormal CTG, a second line of assessment of fetal oxygenation has been advocated and commonly this is in the form of intermittent fetal blood sampling for pH and blood gas analysis; for this, a drop of blood has to be aspirated from the fetal scalp after it is lacerated with a small scalpel.

Another means of assessing oxygenation is by pulse oxymetry, but this is not as yet in established use in obstetrics. This method non-invasively measures transcutaneous oxygen saturation (P_aO_2 sat) by a photometric technique: Light of the red and infra-red spectrum of wavelengths is emitted from a diode through human tissue and is

absorbed to varying degrees by the major source of tissue pigment, which is hemoglobin in the red cells of the capillaries. Oxygenated and de-oxygenated hemoglobin absorb light at different wavelengths, and the absorption spectrum changes according to the level of oxygenation. A second diode acts as a photodetector and the energy of the received light at two different wavelengths is computed to show the $P_aO_{2\ sat}$. The pulse is also recorded through the receiving diode and the peak of the pulse wave is correlated with the incoming light thus preferentially recording the oxygen saturation of arterial blood.

To date, oximetry is in established use in anaesthesia, critical care and neonatal intensive care. The transcutaneous sensors are either placed to transilluminate tissue, e.g. on a finger or, more recently, adapted to also measure reflected light, e.g. on the patient's forehead. Good contact is essential for reliable readings, and on an external surface the device can be easily held down or secured e.g. with adhesive tape.

Use of reflectance oximetry to measure fetal oxygenation during labour would appear to be a valuable form of monitoring and theoretically possible but technically difficult because of the problem of attaching the diodes to the fetal scalp so as to ensure good contact and no movement against the skin surface.

Currently, only intermittent readings are possible whilst the investigator manually holds the diode pads in place on the fetal scalp through the open maternal cervix. Suction cups and glues have been proposed to try to keep the probe in place. Amniotic fluid and fetal hair are amongst the problems for adequate contact.

It is an object of this invention to bring the two described modes of monitoring, i.e. electronic fetal heart rate recording and measurement of fetal oxygen saturation, together by the use of a single probe which integrates sensors for both functions.

Accordingly, the present invention consists in one aspect in a fetal probe comprising a probe body with a probe surface adapted to be positioned in flat-wise contact with the fetal scalp, photo transmitter/receiver means provided in the probe at said surface for use in determining fetal blood oxygenation through light absorption; fastener means for releasably holding said probe surface in flat-wise contact with the fetal scalp; electrode means provided in the body for establishing electrical contact with the scalp for electrocardiography and a probe lead extending from the body and establishing electrical contact with said photo transmitter/receiver means and said electrode means.

Advantageously, said fastener means comprises at least one metal spur moveable relatively to the probe body to pierce and to grip scalp skin.

In a particular form of this invention, the probe is held in place by two thin curved metal wires on either end of the diodes or other photo transmitter/receiver means. By turning a handle on the probe lead, these two wires can be rotated simultaneously to embed superficially into the fetal skin. The use of two wires at either end of the probe gives stability and good contact between the probe surface and the fetal scalp. This stability is essential for reliable measurement of oxygen saturation.

A preferred feature of the invention is that both the metal wires which attach to the fetal scalp can act as electrodes through which a strong, reliable signal can be obtained for continuous electrocardiographic monitoring of the fetus. A strong fetal heart signal is not only important for continuous CTG monitoring, but at the same time it improves pulse oximetry which depends on coordination of measured oxygen saturation with the peak of the fetal pulse.

The current practice of inferring fetal heart pulses from the amplitude of the oximetry signal, can be unsatisfactory in certain circumstances.

In an alternative form of this invention, the fastener means comprises means for dispensing adhesive.

The assurance of a stable configuration of a fetal probe relative to the fetal scalp would enable the use of other sensors currently discounted for obstetrics use. One example is temperature sensors. Accordingly, it is an object of a further aspect of the present invention to provide an improved fetal probe offering a generally stable configuration when in use on the fetal scalp.

Thus, in a further aspect, the present invention consists in a fetal probe comprising a probe body with a probe surface adapted to be positioned in flat-wise contact with the fetal scalp; sensor means provided in the body at said surface for use in monitoring fetal parameters; fastener means for releasably holding said probe surface in flat-wise contact with the fetal scalp and a probe lead extending from the body and establishing electrical contact with said sensor means, wherein said fastener means comprises a pair of metal spurs positioned at opposite sides of said sensor means each being remotely actuable through the probe lead to pierce and to grip fetal scalp skin thereby to retain said sensor means in a generally stable configuration with relation to the fetal scalp.

This present invention will now be described, by way of example, with reference to the accompanying drawings, in which:-

Figure 1 is a side view of a fetal probe according to this invention;

Figure 2 is a plan view of the probe of Figure 1;

Figures 3 to 6 are views showing respective component parts of the probe of Figure 1;

Figures 7, 8 and 9 are plan views of three different further embodiments of fetal probe according to this invention; and

Figure 10 is a block diagram illustrating the interconnection of a fetal probe according to this invention with monitoring equipment.

Referring initially to Figures 1 to 6, a probe according to this invention has a probe body 10 formed of matching component parts 12 and 14. These are moulded from an appropriate plastics material. The base part 12 is formed with recesses 16 and 18 shaped to receive, respectively, a light emitting diode 20 and a photo diode 22. A central channel 24 in the base part 12 opens to one end of the base part and communicates with semi-circular grooves 26 formed at respective opposite sides of the recesses 16, 18. A wire 28 lies in the channel 24 with arcuate spurs 30 formed on the wire 28 being received respectively in the semi-circular grooves 26. As shown best in Figure 6b), the spur 30 at the end of the wire 28 can conveniently be formed integrally with the wire; the other spur 30 is formed with a wire stub 32 bonded in a suitable fashion to the wire 28. This method of construction has the advantage of providing torsional stiffness in that region of the wire lying within the probe body 10.

The cover part 14 of the probe body is formed with windows 34 which are in register with the LED 20 and the photo diode 22, respectively. There are also formed in the cover part 14 two pairs of apertures 36. These are positioned at opposite ends of the semi-circular grooves 26 so as to permit the free ends of the spurs 30, on rotation of the wire 28, to travel from the semi-circular groove 26 out of one of the apertures 36 and return through the other aperture of the pair.

The probe lead 38 comprises a cylindrical section 40 which surrounds the wire 28 and which may, for example, be of a coiled spring construction. The end of the lead section 40 adjacent the probe body is provided with an anchoring pin 42 which is received in a recess (not shown) within the probe body to prevent relative rotation between the lead section 40 and the probe body. At the opposite end of the lead section 40, there is provided a rotatable collar 44. By rotation of this collar, the wire 28 and therefore the spurs 30 can be rotated relatively to the probe body. The arrangement is such that in the rest position, the spurs 30 take the position shown in Figure 2,

that is to say fully extended from the probe body. Rotation of the collar 44 acts against the torsional resistance in the wire to retract the spurs 30 into the semi-circular grooves 26.

In use of the described fetal probe, the probe body 10 is positioned on the fetal scalp. As best seen in Figure 1, the probe surface 46 is slightly concave to conform with the curvature of the fetal head. With pressure from the examiner's finger exerted on the probe body to bring it into contact with the fetal scalp, the collar 44 is rotated to retract the two spurs 30 and allow the probe body to move into flat-wise contact with the fetal scalp skin. With pressure still exerted, the collar 44 is released allowing the spurs, under the action of the torsional resilience of the wire, to pierce the scalp skin superficially.

The manner in which the described probe is connected with remote monitoring equipment will now be described with reference to Figure 10.

The wire 28 is connected through lead 50 with the ECG input of a fetal heart monitor 52. In the described example this is the commercially available fetal heart monitor Hewlett Packard 8040 A. The conductors in the probe lead 38 associated with the LED 20 and photo diode 22 are taken to the input of an oximetry monitor 54. In the described example, this is a commercially available oximeter Criticare CSI 504 US. The oximeter 54 also receives an ECG input from the fetal heart monitor 52 and the output of the oximeter is conveniently connected to the printer associated with the fetal heart monitor. The manner of operation of both the oximeter and the fetal heart monitor are well understood by those skilled in the art and further description is unnecessary. The printer within the fetal heart monitor is conveniently arranged to produce three separate traces: an ECG trace 56 and oxygen saturation trace 58 and a tocograph 60.

It will be recognised that the combination within a single probe of, essentially, an oximetry sensor and an ECG electrode, offers important clinical advantages. The use of two metal spurs to hold the probe surface in flat wise contact with the fetal scalp enables reliable oximetry measurements to be made. As has been noted, advantage can be taken of this effect in fetal probes utilising sensors other than oximetry sensors and it will be possible in a modification to replace the LED 20 and photo diode 22 with, for example, a temperature sensor.

Whilst the use of two metal spurs is regarded as having important advantages, the invention is not so restricted and reference is directed, for example, to Figure 7 in which a single spur 30 is provided. Optionally, the probe body 10 in this embodiment is provided with a flexible cuff 60 about the periphery of probe surface 46. This cuff is compressed as the spur 30 is rotated into engagement with the fetal scalp skin and serves both to stabilise the probe body and to prevent foreign matter entering between the probe surface and the fetal scalp.

In a further modification illustrated in Figure 8, the probe surface 46 contains a plate electrode 62 for ECG. Around the three sides of the probe body remote from the lead, the probe surface 46 is provided with a channel 64 into which appropriate adhesive can be dispensed once the probe is correctly positioned on the fetal scalp. A minor modification is illustrated in Figure 9 in which the ECG electrode 62 is positioned between the LED 20 and the photo diode 22.

It should be understood that this invention has been described by way of examples only and a wide variety of further modifications are possible without departing from the scope of the invention. Thus, for example, whilst the use of LED and photo diode pairs is established in reflectance oximetry, it will be possible to use other photo transmitter-receiver means. In one example, fibre optics can be employed, with the light source and detector remote from the probe body.

CLAIMS

1. A fetal probe comprising a probe body with a probe surface adapted to be positioned in flat-wise contact with the fetal scalp, photo transmitter/receiver means provided in the probe at said surface for use in determining fetal blood oxygenation through light absorption; fastener means for releasably holding said probe surface in flat-wise contact with the fetal scalp; electrode means provided in the body for establishing electrical contact with the scalp for electrocardiography and a probe lead extending from the body and establishing electrical contact with said photo transmitter/receiver means and with said electrode means.

2. A probe according to Claim 1, wherein said fastener means serves additionally as said electrode means.

3. A probe according to Claim 1 or Claim 2, wherein said fastener means is remotely operable through the probe lead to grip fetal scalp skin.

4. A probe according to Claim 3, wherein said fastener means comprises at least one metal spur movable relatively to the probe body to pierce and to grip scalp skin.

5. A probe according to Claim 4, wherein said fastener means comprises two metal spurs each movable relatively to the probe body to pierce and to grip scalp skin, said metal spurs being positioned at opposite sides of said photo transmitter/receiver means.

6. A probe according to Claim 4 or Claim 5, wherein each metal spur is of arcuate form and is rotatable generally about the arcuate axis relatively to the probe body.

7. A fetal probe comprising a probe body with a probe surface adapted to be positioned in flat-wise contact with the fetal scalp; sensor means provided in the body at said surface for use in monitoring fetal parameters; fastener means for releasably holding said probe surface in flat-wise contact with the fetal scalp and a probe lead extending from the body and establishing electrical contact with said sensor means, wherein said fastener means comprises a pair of metal spurs positioned at opposite sides of said sensor means each being remotely actuable through the probe lead to pierce and to grip fetal scalp skin thereby to retain said sensor means in a generally stable configuration with relation to the fetal scalp.

8. A probe according to Claim 7, wherein electrical contact is established through said probe lead with either or both of said metal spurs for use in electrocardiography.

9. A probe according to Claim 7 or Claim 8, wherein said sensor means function optically.

10. A probe according to Claim 9, wherein said sensor means comprises photo transmitter/receiver means for use in determining fetal blood oxygenation through light absorption.

AMENDED CLAIMS

[received by the International Bureau on 26 January 1990 (26.01.90) original claims 1 and 3-10 replaced by amended claims 1 and 3-8, claim 2 unchanged (2 pages)]

1. A fetal probe comprising a probe body with a probe surface; photo transmitter/receiver means provided in the probe at said surface for use in determining fetal blood oxygenation through light absorption; electrode means provided in the body for establishing electrical contact with the scalp for electrocardiography; a probe lead extending from the body and establishing electrical contact separately with said photo transmitter/receiver means and said electrode means and fastener means for releasably holding said probe surface in contact with the fetal scalp, said fastener means comprising two metal spurs positioned at opposite sides of said photo transmitter/receiver means and adapted to pierce and to grip scalp skin thereby to hold said probe surface in flat-wise contact with the fetal scalp.

2. A probe according to Claim 1, wherein said fastener means serves additionally as electrode means.

3. A probe according to Claim 1 or Claim 2, wherein said metal spurs are moveable relatively to the probe body under remote operation through the probe lead.

4. A probe according to Claim 3, wherein each metal spur is of arcuate form and is rotatable generally about the arcuate axis relatively to the probe body.

5. A fetal probe comprising a probe body with a probe surface adapted to be positioned in flat-wise contact with the fetal scalp; sensor means provided in the body at said surface for use in monitoring fetal parameters; fastener means for releasably holding said probe surface in flat-wise contact with the fetal scalp and a probe lead extending from the body and establishing electrical contact with said sensor means, wherein said fastener means comprises a pair of metal spurs positioned at opposite sides of said sensor means each being remotely actuable through the probe lead to pierce and to grip fetal scalp skin thereby to retain said sensor means in a generally stable configuration with relation to the fetal scalp.

6. A probe according to Claim 5, wherein electrical contact is established through said probe lead with either or both of said metal spurs for use in electrocardiography.

7. A probe according to Claim 5 or Claim 6, wherein said sensor means function optically.

8. A probe according to Claim 7, wherein said sensor means comprises photo transmitter/receiver means for use in determining fetal blood oxygenation through light absorption.

Fig.1.

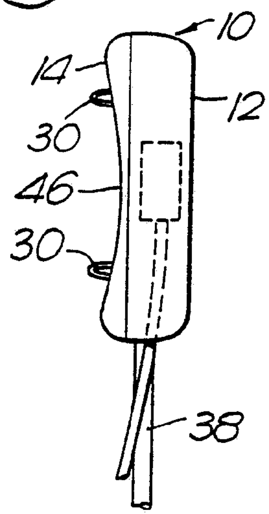


Fig.2.

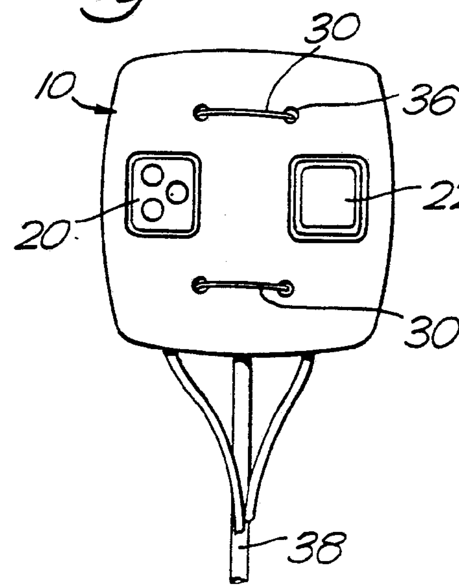


Fig.3.

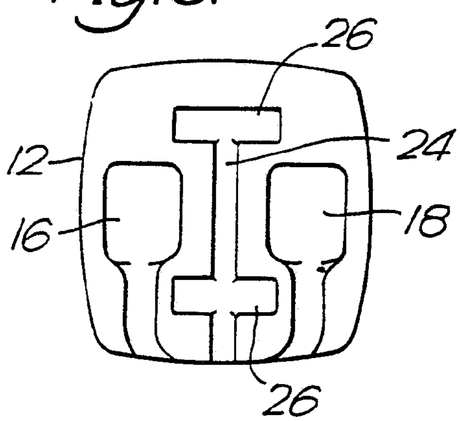


Fig.4.

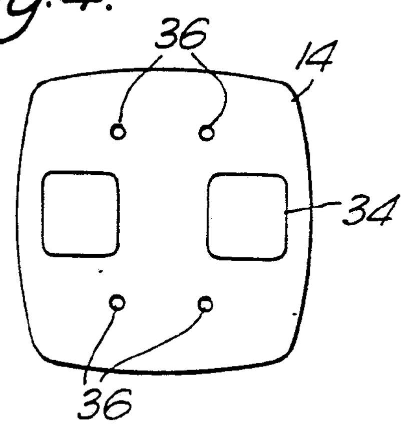


Fig.5.

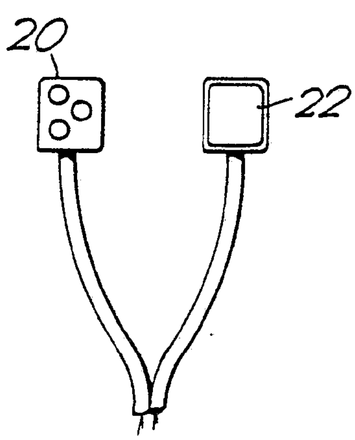


Fig.6b.

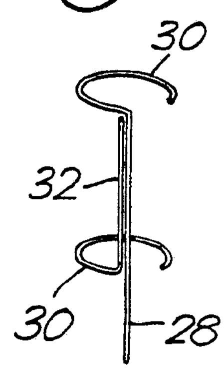


Fig. 7.

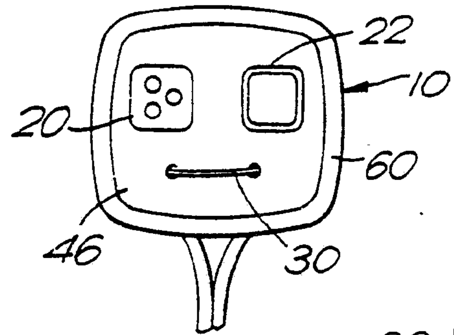


Fig.6a.

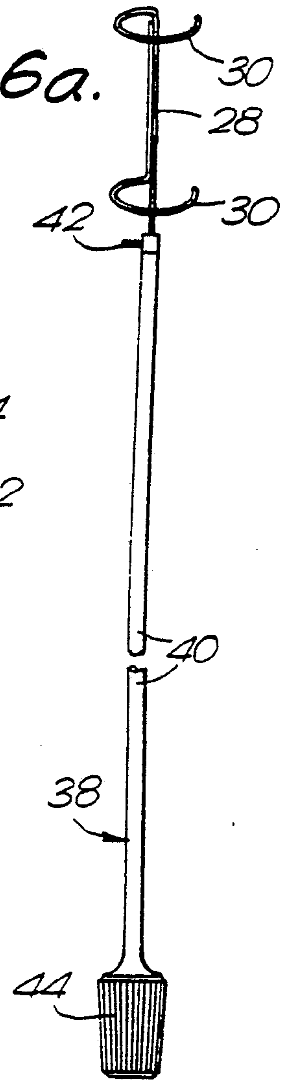


Fig.8.

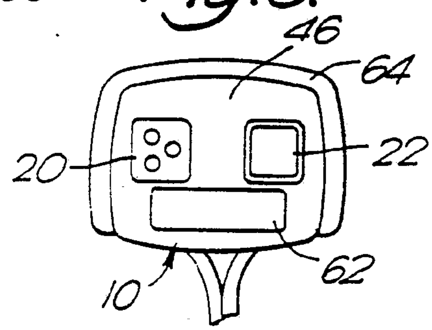


Fig.9.

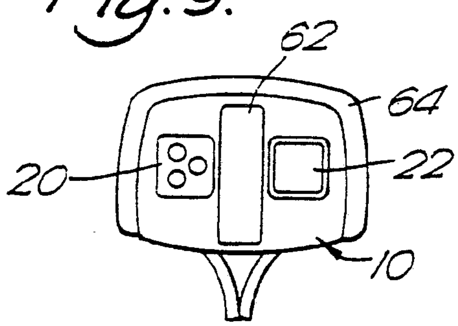
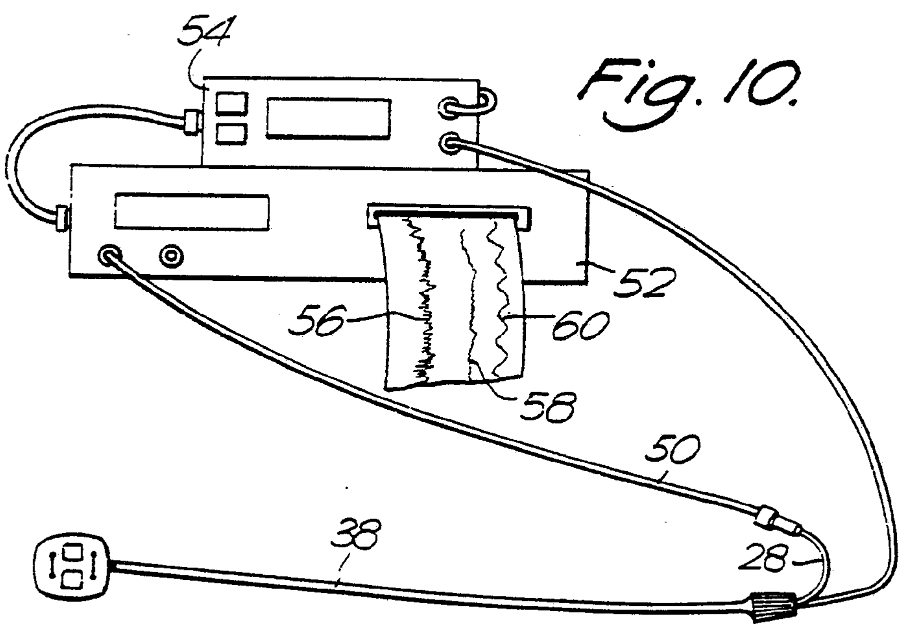


Fig. 10.



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 89/00934

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC^5: A 61 B 5/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC^5	A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [*]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	EP, A, 0104619 (BIOMEDICS INC.) 4 April 1984 see abstract; page 1, lines 21-29; page 2, lines 19-24; page 3, line 16 - page 4, line 14; figures 1-3	1,2
Y		3-8
A		9,10
	--	
Y	US, A, 4281659 (A.O. FARRAR et al.) 4 August 1981 see abstract; column 3, lines 48-66; column 7, line 34 - column 8, line 28; column 10, lines 3-38; figures 2A-8B	3-8
	--	
Y	DE, A, 2930663 (C. WOLLERT) 19 February 1981 see page 4, lines 10-24; page 5, lines 8-21; page 6, lines 19-25; page 6, line 34 - page 8, line 20; figures 1,2	1-10
	-- ./.	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
26th October 1989	27. 11. 89
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	T.K. WILLIS

International Application No. PCT/GB 89/00934

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
Y	EP, A, 0135840 (NELLCOR INC.) 3 April 1985 see abstract; page 6, lines 17-29; page 12, line 8 - page 13, line 6; page 15, lines 21-36; page 23, claim 15; figures 4-10 --	1-10
A	GB, A, 2042898 (A.W. SHOWELL (SURGICRAFT) LTD) 1 October 1980 see the whole document ----------	1-4,7,8

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8900934

SA 30764

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The members are as contained in the European Patent Office EDP file on 17/11/89
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A- 0104619	04-04-84	JP-A- 59080230 US-A- 4658825	09-05-84 21-04-87
US-A- 4281659	04-08-81	None	
DE-A- 2930663	19-02-81	None	
EP-A- 0135840	03-04-85	JP-A- 60090535	21-05-85
GB-A- 2042898	01-10-80	None	

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82